

## **I. Remarks**

Claims 1-19 are currently pending.

Claims 1, 3-5, 7, 9, 11-13, and 15 have been amended with this response. Support for the amendments made to the claims is found throughout the instant specification and particularly beginning at page 5, line 26.

## **II. Rejection of the Drawings and Abstract**

In the present Office Action, the Examiner has objected to the drawings, because Figures 9b and 9c do not both disclose an ID and OD. In response to this objection, Applicant proposes that page 12, line 9 be replaced with the statement "FIG. 9c is an enlarged view of the clearance fit of FIG. 9b." It is respectfully submitted that this amendment of the description of the drawings overcomes the Examiner's objection without requiring the necessity of revising the drawings. No new matter is added by this amendment.

In the present Office Action, the Examiner has objected to the Abstract. In response to the rejection, Applicant proposes to replace the present Abstract with the following:

"The present invention relates to surgical fastener systems, and more particularly to surgical fasteners in the form of tacks, and to apparatus and methods for highly reliable application of surgical fasteners for approximation and fixation of tissue and membranes in furtherance of surgical procedures (e.g., Autologous Chondrocyte Implantation) involving cartilage (e.g., knee cartilage) wherein capillary action is used to retain the tack within the cannula." It is respectfully submitted that the proposed Amendment overcomes the Examiner's rejection and that no new matter is added by the present Amendment.

## **III. Claim rejections under 35 U.S.C. § 112**

In the Office Action, the Examiner has rejected claims 1-19 under the second paragraph of 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner recites that Claims 1 and 9 recite the limitation "predetermined distance is defined between the surgical fastener and inner diameter of the cannula." Applicant intends this

to mean the distance between the outer diameter of the fastener over the majority of the shaft to inner diameter of cannula. However, this could also be interpreted as the distance between the protrusions to the inner diameter of the cannula, thus making the claims indefinite. All dependent claims have been rejected for being dependent to an indefinite claim.

In response to this rejection, Applicant has amended each of the affected claims by removing all reference to "predetermined distance". It is respectfully submitted that this amendment of the claims overcomes the potential confusion identified by the Examiner.

#### **IV. Claim rejections under 35 U.S.C. § 102**

In the present Office Action, claims 1, 3, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummings et al (US Patent 6,322,563). The Examiner rejected these claims by asserting that Cummings et al clearly anticipates a bioabsorbable fastener assembly comprising an applicator including a loading tip, carrier assembly removably mounted within the loading tip, cannula having an inner and outer diameter, and a surgical fastener (and surface feature) disposed within the cannula. Furthermore, the Examiner asserts that in its broadest reasonable interpretation, the "friction fit" of Cummings et al is a "clearance fit" of applicant because the fastener was still capable of being fit within the cannula and thus had "clearance." As for the fluid being in communication with at least one positive surface feature, this is inherently the case with Cummings et al when considering surgery. Bodily fluids will excrete and be drawn into the device to fill any gaps present between the fastener and cannula.

In order for the Cummings et al reference to be a proper anticipatory reference, each and every element of the claimed invention must be disclosed in the cited reference. It is respectfully submitted that the Examiner has improperly ignored the feature relating to "...the presence of the fluid defines a meniscus that induces a capillary force between the surgical fastener and the inner diameter of the cannula to retain the surgical fastener within the cannula prior to deployment of the fastener into the tissue of a patient." It is respectfully submitted that nothing in Cummings et al discloses the "fluid" or the "capillary force" described in the present application and as set forth in the rejected claims. Because claims 3, 6 and 8 are dependent on independent claim 1, it is respectfully submitted that these claims are not anticipated by the cited reference.

## V. Claim rejections under 35 U.S.C. § 103

In the present Office Action, Claims 2, 4, 5, 7, and 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al in view of *Using Parylene for Medical Substrate Coating* (<http://www.devicelink.com>).

The Examiner asserts that the only differences present between applicants device and Cummings et al are a larger clearance between the tack and cannula and the use of a hydrophobic liquid. The website teaches that coatings for products including bone pins, prosthetic hardware, catheters, needles, medical probes, and various other implants are known in the art. Reasons include physical isolation from moisture, chemicals, and other substances; surface passivation; electrical insulation; tie-down of microscopic particles; and reduction of friction. It further goes on to say typical coatings are solvent-based liquid resins such as epoxies, silicones, acrylics, and urethanes and that these types of coatings exhibit liquid properties including: pooling, bridging between adjacent surfaces, and exhibiting meniscus forces. From applicant's own admission, the issue with Cummings et al's device was that friction may have been too great and not allowed for detachment of the tack in relation to the cannula. Thus it would have been obvious to one of ordinary skill in the art to have coated Cummings et al's device with a liquid such as silicone to in the least reduce friction, if not also protect the tack.

The Examiner further asserts that in regard to claims 4, 5, 7, 12, 13, and 15 due to the nature of the Cummings et al. device becoming jammed, a more readily obvious design choice of increasing the clearance between the two components is known. Even children are able to realize if two parts are sticking together due to a friction fit, you can make one smaller than the other. Thus, the dimensions applicant has claimed are deemed obvious dimension optimizations in order to retain a fit between the components while avoiding over slippage. This task is well within the skill of one of ordinary skill in the art.

Reconsideration of this rejection is respectfully requested. In order for the Examiner to properly support an obviousness rejection, there must be some teaching or suggestion to support the combination asserted by the Examiner. It is respectfully submitted that the Examiner has failed to provide a proper showing of the necessary teaching or suggestion. It is

respectfully submitted that the Examiner has improperly searched for the missing element and then supplied the missing element in accordance with the teachings of the present application. It is respectfully submitted that there is nothing in the Cummings et al reference that would suggest anything other than modifying the dimensions of the fastener in order to overcome a potential problem with the tack being frictionally retained in the cannula and causing difficulties during insertion. The Examiner has previously referenced the use of body fluids to alleviate sticking difficulties. In response to this rejection, Applicant has clarified the claims so that it is clear that a liquid is present prior to insertion into the patient. In claim 9, the liquid is described as being in communication with at least a portion of the surgical fastener prior to the fastener being at least partially introduced into the cannula. It is respectfully submitted that nothing in Cummings et al supports the approach provided by the Examiner. The mere fact that the Examiner has identified a reference that states various products may be coated and that those products may be coated for a number of reasons, is not sufficient to support the assertion that the claims of the present application are obvious in view of these general, non-specific teachings. It is respectfully submitted that the combination asserted by the Examiner could have only been created by relying on the teachings of the present application. As the Examiner indicates, many devices could be coated with many materials for many reasons. It is respectfully submitted that a proper obviousness rejection must be more specific than the combination created by the Examiner. As the Examiner asserts with respect to the rejection of claims 4, 5, 7, 12, 13 and 15, a more obvious design choice of increasing the clearance between two components is known. It is respectfully submitted that the use of a fluid to create a meniscus that induces a capillary force is not taught or suggested by the combination of references formed by the Examiner. Furthermore, the Examiner has failed to address the limitation relating to the use of "at least one positive surface feature" as set forth in claims 6, 7, 14 and 15.

In view of the foregoing, the prompt issuance of an indication of the allowability of claims 1-19 is respectfully requested. In the event that the Examiner is unclear about any of the Amendments to the claims, the Examiner is respectfully requested to contact Applicant's Attorney at the telephone number indicated below.

## **VI. Claim Amendments under 37 C.F.R. § 1.121**

1.(Currently Amended) A surgical fastening assembly comprising:

an applicator including a loading tip;

a carrier assembly removably mounted within the loading tip;

a cannula having an inner diameter and an outer diameter, the cannula being disposed within the carrier assembly; and

a surgical fastener having a shaft portion and wherein the surgical fastener is disposed at least partially within the cannula such that a predetermined distance is defined between the surgical fastener and the inner diameter of the cannula, and wherein at least a portion of the surgical fastener is in communication with a fluid, and wherein the presence of the fluid defines a meniscus that induces a capillary force between the surgical fastener and the inner diameter of the cannula to retain the surgical fastener at least partially within the cannula prior to deployment of the fastener into the tissue of a patient.

2.(Original) The surgical fastening assembly of claim 1, wherein the fluid is a biocompatible hydrophobic fluid.

3.(Currently Amended) The surgical fastening assembly of claim 1, wherein the ~~predetermined~~ distance between the outer diameter of the fastener over the majority of the shaft to the inner diameter of the cannula is selected to enable a clearance fit to be formed between the surgical fastener and the inner diameter of the cannula.

4.(Currently Amended) The surgical fastening assembly of claim 3, wherein the ~~predetermined~~ distance between the outer diameter of the fastener over the majority of the shaft to the inner diameter of the cannula is between about 0.0025 inch and 0.006 inch.

5.(Currently Amended) The surgical fastening assembly of claim 4, wherein the predetermined distance between the outer diameter of the fastener over the majority of the shaft to the inner diameter of the cannula is about 0.003 inch.

6.(Original) The surgical fastening assembly of claim 1, wherein the surgical fastener includes at least one positive surface feature, and wherein the fluid is in communication with at least one of the at least one positive surface feature.

7.(Currently Amended) The surgical fastening assembly of claim 6, wherein the presence of the at least one positive surface feature reduces the predetermined distance between the outer diameter of the fastener over the majority of the shaft to the inner diameter of the cannula by approximately 66% at the at least one positive surface feature.

8.(Original) The surgical fastening assembly of claim 1, wherein the surgical fastener is formed from a bioabsorbable material.

9.(Currently Amended) A method of introducing a surgical fastener into an implantation site, comprising the steps of:

providing a surgical fastener having a shaft portion;

providing a cannula having an inner diameter and an outer diameter;

placing fluid into communication with at least a portion of the surgical fastener;

at least partially introducing the surgical fastener into the cannula such that the portion of the surgical fastener that is in communication with the fluid is disposed within the cannula ~~and such that a predetermined distance is defined between the surgical fastener and the inner diameter of the cannula~~;

allowing the presence of the fluid to define a meniscus that induces a capillary force between the surgical fastener and the inner diameter of the cannula to retain the surgical fastener at least partially within the inner diameter of the cannula; and

causing the surgical fastener to be deployed from within the cannula and into an implantation site wherein the capillary force allows the surgical fastener to be released from within the cannula.

10.(Original) The method of claim 9, wherein the fluid is a biocompatible hydrophobic fluid.

11.(Currently Amended) The method of claim 9, wherein the ~~predetermined~~ distance between the outer diameter of the surgical fastener over the majority of the shaft to the inner diameter of the cannula is selected to enable a clearance fit to be formed between the surgical fastener and the inner diameter of the cannula.

12.(Currently Amended) The method of claim 11, wherein the ~~predetermined~~ distance between the outer diameter of the surgical fastener over the majority of the shaft to the inner diameter of the cannula is between about 0.0025 inch and 0.006 inch.

13.(Currently Amended) The method of claim 12, wherein the ~~predetermined~~ distance between the outer diameter of the surgical fastener over the majority of the shaft to the inner diameter of the cannula is about 0.003 inch.

14.(Original) The surgical fastening assembly of claim 9, wherein the surgical fastener includes at least one positive surface feature, and wherein the fluid is in communication with at least one of the at least one positive surface feature.

15.(Currently Amended) The surgical fastening assembly of claim 14, wherein the presence of the at least one positive surface feature reduces the ~~predetermined~~ distance between the outer diameter of the surgical fastener over the majority of the shaft to the inner diameter of the cannula by approximately 66% at the at least one positive surface feature.

16.(Original) The method of claim 9, wherein the step of placing fluid into communication with at least a portion of the surgical fastener is at least partially accomplished through the use of an applicator.

17.(Original) The method of claim 16, wherein the applicator is selected from the group consisting of a brush-type applicator and a spray-type applicator.

18.(Original) The method of claim 9, wherein the step of placing fluid into communication with at least a portion of the surgical fastener is at least partially accomplished through dipping the portion of the surgical fastener into a containment element that contains the fluid.

19.(Original) The surgical fastening assembly of claim 9, wherein the surgical fastener is formed from a bioabsorbable material.

**VI. Specification Amendments under 37 C.F.R. § 1.121**

A) Please replace the abstract of the instant specification with the following replacement abstract:

The present invention relates to surgical fastener systems, and more particularly to surgical fasteners in the form of tacks, and to apparatus and methods for highly reliable application of surgical fasteners for approximation and fixation of tissue and membranes in furtherance of surgical procedures (e.g., Autologous Chondrocyte Implantation) involving cartilage (e.g., knee cartilage) wherein capillary action is used to retain the tack within the cannula.

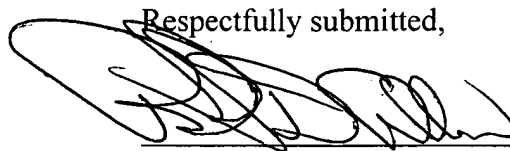
B) Please replace the paragraph on page 12, line 9 of the instant specification that begins with "FIG. 9c is an enlarged view of the clearance fit of FIG. 9b" with the following replacement:

FIG. 9c shows an enlarged view of one embodiment of a carrier assembly holding a tack in accordance with the present invention.

### **VIII. Conclusion**

No fee is deemed necessary in connection with the filing of this communication other than the two month extension of time to file the present response. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

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Date

Respectfully submitted,  


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